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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket # 98N-1038, "Irradiation in the Production, Processing, and Handling of Food"

To whom it may concern:

I am addressing my comments as an individual consumer and as a medical psychologist who is concerned with nutritional effects on physical, mental and emotional functioning.

The FDA should retain the current labeling law, the current terminology of "treated with radiation" or "treated by irradiation," and the use of the radura symbol on all irradiated whole foods.

What follows are my comments to the questions for which the FDA is seeking input:

(1) Does the current radiation disclosure statement convey meaningful information to consumers in a truthful and nonmisleading manner?

The current terminology of "treated with radiation" or "treated by irradiation" is truthful and nonmisleading. Food irradiation is known to produce changes in texture, taste, shelf life, nutritional or vitamin content, and the creation of new chemical substances in the food known as radiolytic products which may be known to be toxic (such as benzene) or else untested for toxicity. These changes are not obvious or expected by a consumer. There have been no long-term human studies to determine the effects of eating irradiated foods.

The current FDA labeling requirement for irradiated foods states that a radiation disclosure statement is not required to be any more prominent than the required declaration of ingredients. Since food irradiation can have a significant impact on a food, to me it is misleading to allow the declaration of irradiation to be limited to the size type of the listing of food ingredients, which is often printed in a type that is so small it is difficult for the average person to read. Rather than eliminating the requirement for disclosure of food irradiation, labeling of this fact should be printed separately from the list of ingredients, ideally in a larger type size.

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(2) How do consumers perceive the current radiation disclosure statement--as informational, as a warning, or as something else?

I believe that most consumers have not even seen the current radiation disclosure statement on a food product. I do not recall seeing such a label. I believe that consumers would perceive such a label as helpful, and it would provide them with useful information which allow them to determine whether or not they wished to purchase a product that had been irradiated.

(3) Does the wording of the current radiation disclosure statement cause "inappropriate anxiety" among consumers? What are examples of "inappropriate anxiety"?

I do not believe that consumers would believe that "treated with radiation" or "treated by irradiation" meant that a food was actually radioactive. I believe that food producers have "inappropriate anxiety" that consumers will not purchase products treated by irradiation when given the opportunity to make an informed decision based on clear labeling.

(4) What specific alternate wording for a radiation disclosure statement would convey meaningful information to consumers, in a truthful and nonmisleading manner, and in a more accurate or less threatening way than the current wording?

Anything less than the current radiation disclosure statement would be misleading, particularly the use of terms such as "cold pasteurization" or "electronic pasteurization," since such terms would be associated with heat pasteurization rather than irradiation. Heating a liquid to a desired temperature for a specific amount of time (pasteurization) is **not** the same as exposing food to radioactive materials.

(5) Would consumers be misled by the absence of a radiation disclosure statement in the labeling of irradiated foods? Are consumers misled by the presence of such a statement?

Consumers would be misled by the absence of a radiation disclosure statement in the labeling of irradiated foods and would believe that the food had not been irradiated.

Consumers are only misled by the presence of such a statement when it is printed in such small type that it is not seen by an individual who does not take the time to read the entire list of ingredients or who does not have sufficient vision to read small print.

The disclosure statement should be large enough to be readily visible to the consumer on the front of the package.

If a food is not packaged, disclosure information should be clearly displayed on an easily seen display in plain view adjacent to where the product is displayed for sale.

(6) With respect to foods containing irradiated ingredients, are consumers misled by the absence of a radiation disclosure statement? Would consumers be misled by the presence of such a statement?

Consumers are definitely misled by the absence of a radiation disclosure statement in foods containing irradiated ingredients, since food irradiation can materially affect food properties such as taste and texture and can also cause chemical changes in the food which are not evident and which are potentially hazardous. If there is no label or disclosure statement, consumers will be misled into believing that none of the ingredients in the food have been irradiated.

Consumers would not be misled by the presence of such a statement, especially when the statement stated exactly which ingredients had been subject to irradiation.

(7) What is the level of direct consumer experience with irradiated foods that are labeled as such?

I do not recall seeing any labeled irradiated foods.

(8) What is the effect of the current required labeling on the use of irradiation? Does the current required labeling discourage the use of irradiation?

According to a CBS poll in 1997, 77% of those polled stated that they did not want irradiated foods. Requiring labeling on the use of radiation allows consumers to make an informed decision about the foods that they purchase. If there is no demand for irradiated foods, then food processors have no incentive to bring such products to the marketplace. The use of required labeling should not be discontinued as a means to provide those who stand to profit from food irradiation such as those in the food processing or the nuclear industries. The decision on whether or not to purchase foods which have been treated with radiation should not be taken away from the consumer by the removal of required labeling on the use of irradiation.

(9) What do consumers understand to be the effect of irradiation on food? For example, what do consumers understand about the effect of irradiation on the numbers of harmful microorganisms in or on food?

I understand that a radiation does not eliminate 100 percent of potentially dangerous bacteria from food, and that even food which has been irradiated such as meat which is not handled or stored properly can become contaminated. Because bacteria which give meat a spoiled smell are destroyed in the radiation process, the consumer might use such a product which he or she otherwise would have thrown away due to obvious spoilage. Consumers are not generally aware that irradiation kills both bad and good germs, destroys nutrients, enzymes, and creates radiolytic products, some of which are known to be carcinogenic and mutagenic. Since irradiation may not kill all dangerous microbes, organisms which survive the radiation process have become radiation-resistant. No research has been done to determine what the effect of radiation-resistant bacteria and their progeny populating the intestines would be on consumers. Radiation-resistant strains of salmonella have been developed under laboratory conditions, and scientists at Louisiana State University in Baton Rouge found that one bacteria occurring in spoiled meat and animal feces can survive irradiation doses five times what the FDA proposes to treat beef with.

(10) Do consumers readily recognize the radura logo?

No.

(11) Do consumers understand the logo to mean that a food has been irradiated?

No.

(12) Do consumers perceive the radura logo as informational, as a warning, or as something else?

Due to the current limited use of the radura logo, people do not recognize or understand it, so it provides no meaningful information to them.

(13) Should any requirement for a radiation disclosure statement expire at a specified date in the future?

Requirement for a radiation disclosure statement should never expire, because the facts of the adverse effects of food irradiation on food chemistry will not change, and because consumers should always be given informed consent of whether or not they wish to purchase a food that has been treated with irradiation. Widespread use of food irradiation is a new technology, and there is a great need to assess the health effects of the use of a variety of irradiated foods in the human diet.

In its initial petition, the FDA concluded that irradiation was a "material fact" about the processing of a food and thus should be disclosed:

As discussed in both the 1986 final rule and the 1988 response to objections, FDA concluded that labeling of irradiated foods was necessary because such processing is a material fact that must be disclosed to the consumer to prevent deception. The agency determined that irradiation is a form of processing that can produce significant changes in certain characteristics of a food, such as the organoleptic (e.g., taste, smell, texture) or holding properties, in a manner that is not obvious to the consumer in the absence of labeling. That is, in the absence of labeling indicating that the food has been irradiated, the implied representation to consumers is that the food has not been processed.

Processing by irradiation remains a material fact. Labeling, therefore, should remain.

(14) If so, on what criteria should the expiration be based?

There are no justifiable criteria for the expiration of the radiation disclosure statement.

(15) If the expiration of labeling requirements for irradiated foods is to be based on consumer familiarity with the radura logo and understanding of its meaning, what evidence of familiarity and understanding would be sufficient to allow these requirements to expire?

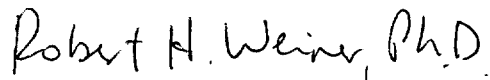
I do not perceive that the radura logo will ever become universally known and understood. There is no rationale or justification sufficient for eliminating the labeling requirements for irradiated foods.

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Consumers should continue to have the right to make an informed decision about whether or not they wish to purchase and consume foods which have been subject to irradiation.

I would like the FDA to place the comments received on the Internet so that the public can be informed about who is participating in this comment process and what public opinion is on this matter.

Sincerely,

A handwritten signature in black ink that reads "Robert H. Weiner, Ph.D." The signature is written in a cursive, slightly slanted style.

Robert H. Weiner, Ph.D.

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